K121769

MAR 0 5 2013

Abbreviated 510(k) Summary

1. **Name/Address of Submitter:** **Itena Clinical**
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   FRANCE

2. **Contact Person:** **Louis-Paul Marin**
   Co-President, BCF Certification inc.
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3. **Date Summary Prepared:** **August 25, 2012**

4. **Devices Names:** Dentocore Body, Dentocore
5. **Device Classification:** II
6. **Classification Product Code:** EBF
7. **Common Name:** Dual-cured core built-up material
8. **Regulatory number:** 872.3690

9. **Predicate Device:**

Luxacore/Luxacore Dual	K012307

10. **Devices Description:** The subject devices are dual-cure (auto and photo), nanofilled resin composite materials. They are stackable for easy setting, with no condensation, radio opaque and fluoride releasing.

    The subject devices are presented in an Automix syringe and a Cartridge used with a gun. Dentocore and Dentocore Body have the same intended use; the former possessing a relatively higher viscosity. This quality is a selection criterion for practitioners choosing this type of material.

    The subject devices present numerous advantages, notably the following:

    - Good compressive strength
    - Low polymerization shrinkage
    - Fluorure release
    - Very high radio opacity properties

11. **Indication for Use:** The subject devices are intended to serve for the fabrication of core build-ups. They are also intended to serve as a base cement to affix pins and posts. They may be used with any Bis-GMA compatible bonding agent.

12. **Brief Description of Clinical and Non-clinical Testing:** This submission is an Abbreviated 510(k) as described in FDA's guidance document entitled "The New 510(k) Paradigm – Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications". In support of this, Itena Clinical has provided information to demonstrate conformity with FDA's guidance document entitled Dental Composites – Premarket Notification, November 1998 and ISO 4049 – Dentistry – Polymer-based filling, restorative and luting materials.

    In vitro Cytotoxicity assay have been performed in accordance to ISO 7405:1997 and ISO 10993, using the well-characterized mouse cell line L929 cultured in tissue culture dishes. The Positive and Negative Controls resulted in cell reactions that have been interpreted as Moderate-severe and none, respectively, validating the test. The subject devices were found as non-cytotoxic.

13. **Conclusion Drawn:** Based on their indications for use, technological characteristics and comparison to predicate devices, the subject devices have been shown to be safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 5, 2013

Itena Clinical
C/O Ms. Louis-Paul Marin
Co-President
BCF Certification, Incorporated
500 Boul Cartier West
Laval, Canada H7V 5B7

Re: K121769
Trade/Device Name: Dentocore, Dentocore Body
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: January 16, 2013
Received: February 11, 2013

Dear Mr. Marin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indication for Use

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Concurrence of CDRH Office of Device Evaluation

Prescription Use _X_ **OR** **Over-the-counter Use** ____
(per 21CFR 801.109)

Mary S. Runner -S
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(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K121769